



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Cellular, Tissue and Gene Therapies Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee. This meeting was announced in the Federal Register of October 17, 2012 (77 FR 63840-63841). The amendment is being made to reflect a change in the Date and Time, Agenda, Procedure, and Closed Committee Deliberations portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Gail Dapolito or Sheryl Clark, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 17, 2012, FDA announced that a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee would be held on November 29, 2012. On page 63841, in the first column, the Date and Time portion of the document is changed to read as follows:

The teleconference meeting will be held on November 29, 2012 from 1 p.m. to 4:30 p.m., Eastern Time.

On page 63841, in the first column, last paragraph, the Agenda portion is changed to read as follows:

On November 29, 2012 the committee will meet in open session to hear updates of research programs in the Gene Transfer and Immunogenicity Branch, Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research, FDA.

On page 63841, second column, second paragraph, first sentence, the Procedure portion is changed to read as follows:

On November 29, 2012, from 1 p.m. to 2:30 p.m. (Eastern Time) the meeting is open to the public.

On page 63841, second column, second paragraph, fourth sentence, the Procedure portion is changed to read as follows:

Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m.

On page 63841, second column, third paragraph, first sentence, the Closed Committee Deliberations portion is changed to read as follows:

On November 29, 2012 from approximately 3:30 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: October 23, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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